

ZetrOZ Systems, LLC

Clinical Trial Results
2016-2017 Summary

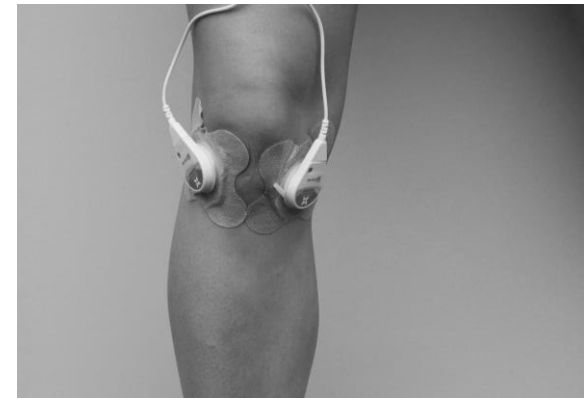
George K. Lewis, Ph.D.
Confidential Information



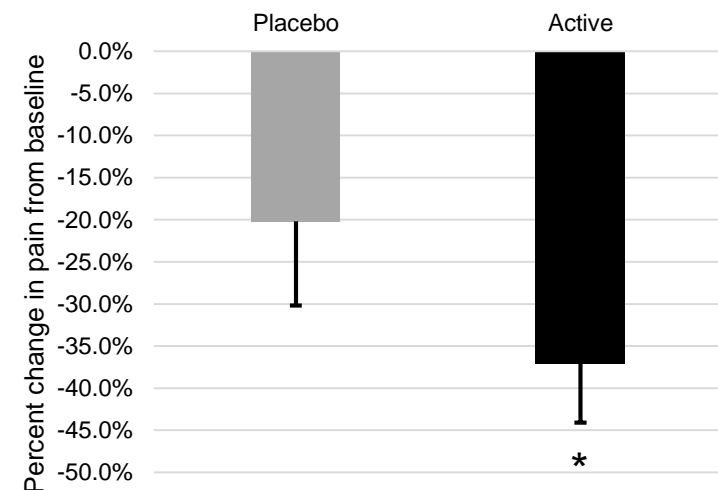
Osteoarthritis: 90-Subject RCT on Pain and Function



- Double-blind randomized controlled clinical trial on knee osteoarthritis.
- 6-weeks of daily sam[®] treatment to knee
- Active (n=55), Placebo (n=35)
- Clinical outcome measures included: Pain (0-10, NRS), pain/function (Western Ontario McMaster Osteoarthritis Questionnaire), function/range of motion (dynamometry)
- **Results:** *Over six-weeks of therapy, pain was significantly reduced in the active group by 2.03-points (37.1%) versus placebo group 1.02-points (20.2%) ($p < 0.05$).*



Percent Pain Reduction by Group

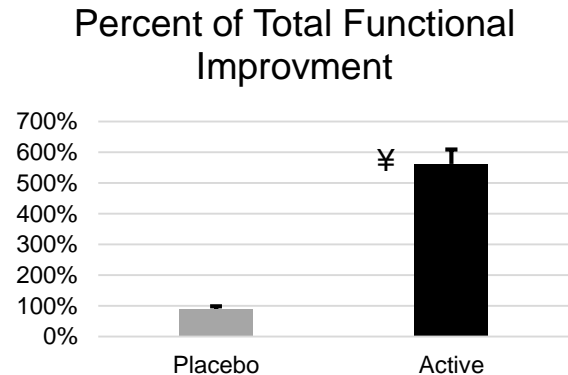
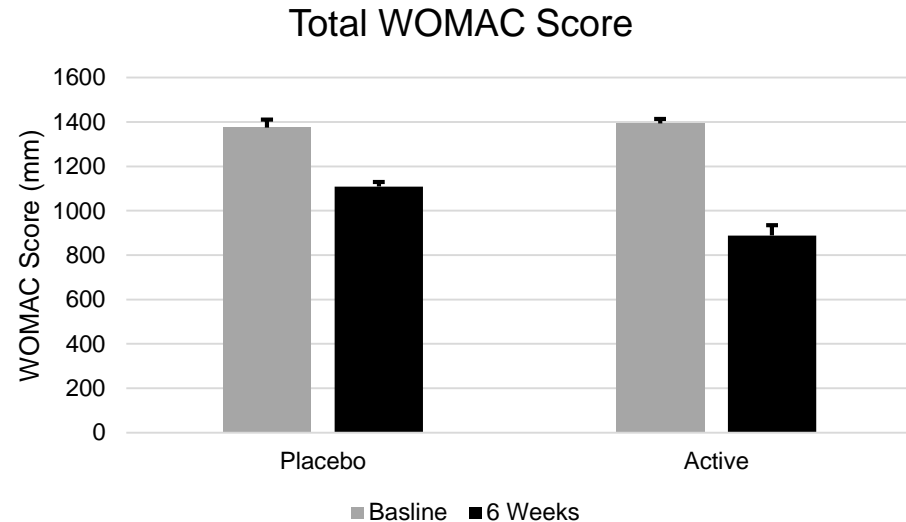


Study funded by the United States
National Institutes of Health

Osteoarthritis: Pain and Function Outcomes



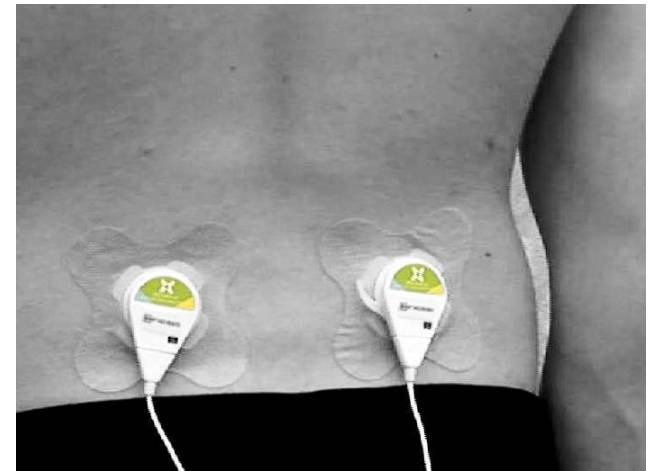
- **Results:** *The Western Ontario McMaster Osteoarthritis Questionnaire (WOMAC) score was significantly improved for all measures of pain, function and stiffness in the treated knee. Active sam[®] treatment showed a 505-point improvement versus a 266-point change for placebo ($p < 0.01$).*
- **Results:** *Range of motion and muscle strength measurements favored Active sam[®] treatment by over 5-times ($p < 0.05$),*



Lower Back Pain from Herniated Disc: 65-Subject RCT on Pain and Stiffness



- Single-blind randomized controlled clinical trial on chronic low back pain secondary to herniated discs
- 8-weeks of daily sam[®] treatment to the lower back
- Active (n=55), Placebo (n=10)
- Clinical outcome measures included: Pain (0-10, NRS) and quality of life improvement (Global Rate of Change -7 to +7)
- **Results:** (analysis still in process) *Over eight-weeks of therapy, pain was significantly reduced in the active group by 2.08-points (30.0%)*



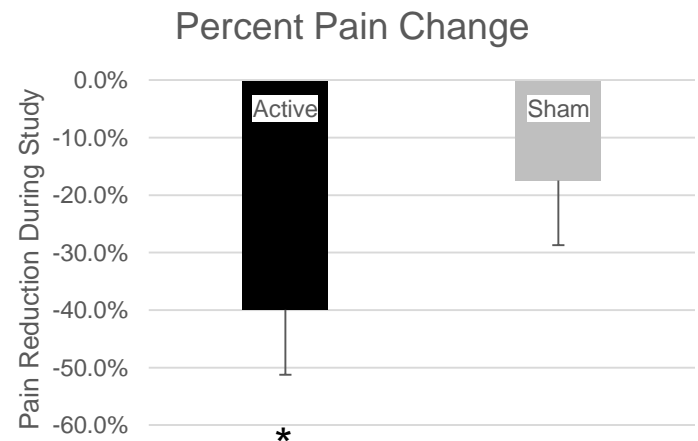
Study funded by United States National Space Biomedical Research Institute



Trapezius Myofascial Pain: 33-Subject RCT on Pain and Quality of Life



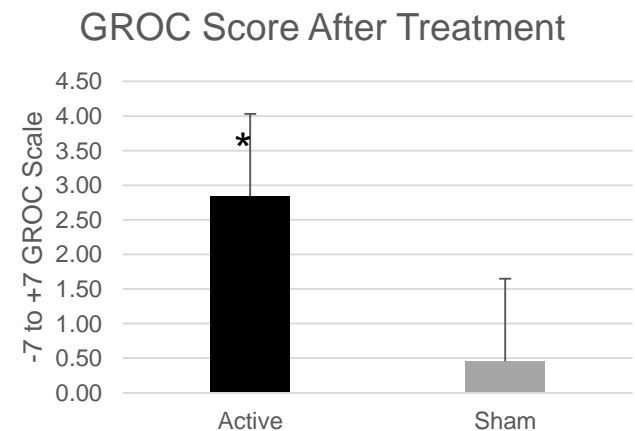
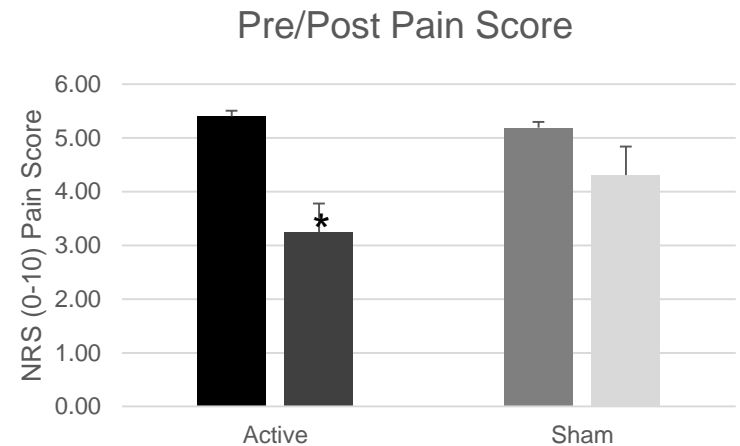
- Double-blind randomized controlled clinical trial on trapezius myofascial pain
- 4-weeks of daily sam[®] treatment to the upper back trapezius muscle group
- Active (n=25), Placebo (n=8)
- Clinical outcome measures included: Pain (0-10, NRS) and quality of life improvement (Global Rate of Change -7 to +7)
- **Results:** *Over four-weeks of therapy, pain was significantly reduced in the active group by 2.15-points (40.0%) versus placebo group 0.88-points (17.4%) ($p < 0.05$).*



Trapezius Myofascial Pain: Pain and Quality of Life Outcomes



- **Results:** *Over four-weeks of therapy, pain was significantly reduced in the active group by 2.15-points (40.0%) versus placebo group 0.88-points (17.4%) ($p < 0.05$).*
- **Results:** *Global rate of change score after treatment was significantly better for the active treatment group (+2.84-points) versus (+0.46-points) for the placebo group ($p < 0.01$).*



Summary and Conclusions



- Recently completed placebo-controlled clinical trials on 188 subjects having chronic pain conditions
- Daily sam[®] therapy reduces chronic joint and back pain by approximately 2 points on the NRS 0-10 pain scale
- Daily sam[®] therapy improves function and quality of life as measured with dynamometry, WOMAC and GROCC scales
- sam[®] is a safe and effective therapy for Osteoarthritis and Upper/Lower back pain